

REMARKS/ARGUMENTS

Status of the claims

Claims 1, 5, 7-23 and 26-28 were previously pending and are canceled without prejudice. Claims 29 to 34 are newly presented. After entry of these amendments, claims 29 to 34 will be pending.

Claims 1, 5, 7-23 and 26-28 stood rejected under 35 U.S.C. 103(a) as being unpatentable over Zavada et al., U.S. Patent No. 5,955,075 (issued September 21, 1999) and further in view of Zisman et al., Journal of Clinical Oncology 19(6): 1649-1657 (2001)) and Belldegrun et al., U.S. Patent Application Publication number 2002/0058041 (published May 16, 2002).

Claims 1, 5, 7-23 and 26-28 under 35 U.S.C. 103(a) as being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (see, above) and Belldegrun et al. (see, above).

Support for the amendments to the claims

Claim	Recital	60/373193
29. (new). A method of	<p>aiding in a renal cell carcinoma prognosis for a human subject</p> <p>diagnosed with locally advanced or metastatic renal clear cell carcinoma, comprising:</p> <p>(a) obtaining a sample of the locally advanced or metastatic lesion of the renal tumor of the subject;</p> <p>(b) determining whether the sample is negative or positive for the expression of the CAIX protein of SEQ ID NO:2; and</p> <p>(c) aiding the prognosis by identifying</p>	<p>Paragraph 7 at p.2, lines 22-23, claim 2</p> <p>Paragraphs 16, 17</p> <p>Claim 2, paragraphs 16, 17</p> <p>Paragraphs 12, 16; support for the recital of SEQ ID NO:2 is inherent; the sequence was known as taught in</p>

	<p>the carcinoma as having a greater malignant potential if the sample is negative for expression of the CAIX protein or identifying the carcinoma as having a lesser malignant potential if the sample is positive for expression of the CAIX protein;</p> <p>(d) and planning a therapy for the patient according to the prognosis.</p>	Paragraphs 27, 29 p.3, line 7
30 (new). The method of claim 29,	wherein the expression of the CAIX protein is determined using immunohistochemical staining.	Paragraph 12
31. (new). The method of claim 29,	wherein the subject has locally advanced renal cell cancer and the sample is negative for CAIX and the therapy is adjuvant immunotherapy	Paragraph 30, p. 10, lines 24 -29
32. (new) The method of claim 29,	wherein the subject has metastasized renal cell cancer and the therapy is adjuvant immunotherapy.	paragraph 15, Page 32, third bullet
33. (new).	<p>A method of aiding in a renal cell carcinoma prognosis, the method comprising:</p> <p>a) obtaining one or more samples derived from a locally advanced renal tumor and/or a metastatic lesion derived from a renal tumor of a human subject diagnosed with locally advanced or metastatic renal clear cell carcinoma;</p> <p>b) immunohistochemically staining the sample for the CAIX protein of SEQ ID NO:2, and</p> <p>c) obtaining the prognosis for the subject according to the results of id staining, wherein a sample which stains negatively indicates a poorer likelihood of survival for the subject than does a sample which stains positively.</p>	Paragraph 7 at p.2, lines 22 -23, claim 2 Claim 2, paragraphs 16, 17 Paragraphs 12, 16 Paragraph 5
34. The method of claim	wherein further the prognosis is used in	p. 2, line 6

33,	the selection of a treatment regimen for the subject	
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The Applicants note that the specification of the 60/373,193 application was incorporated by reference in its entirety by virtue of the recitals of the first sentence of the specification. Accordingly, the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

Priority claim

As set forth above, the amended claims are supported by their earliest priority disclosure. With regard to the subject matter of SEQ ID NO:2, the Applicants further note that the sequence of a protein is inherent to it and that as of the earliest priority date the CAIX amino acid sequence had been published as evidenced by the Zavada et al. patent U.S. Patent No. 5,955,075 cited by the Examiner. Accordingly, the Applicants submit that the present claims enjoy the benefit of the priority claim to the 60/373193 application.

Responses to both rejections under 35 U.S.C. 103(a).

As noted above, the present claims enjoy benefit of the priority date of the 60/373193 priority application. The cited Belldgrun et al. patent publication is not prior art under 35 U.S.C. §102(a) as it was first published in May 2002, after the effective priority date for the amended claims of April 16, 2002. Accordingly, the Applicants respectfully request that these grounds of rejection be reconsidered and withdrawn.

As to any 35 U.S.C. §102(e) concern over the Belldgrun publication, the corresponding patent application was owned by the same Applicants as the instant application at the time the instant invention was made, this reference is subject to the safe harbor provisions of 35 U.S.C. §103(c) as indicated below.

Statement of Common Ownership at the time the instant invention was made

On behalf of the Applicants, the undersigned states that the instant invention of the above-captioned 10/511,465 application and the invention of U.S. Patent Application Publication No. 20020058041 were each owned by the same person or subject to an obligation of

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assignment to the same person at the time the instant invention was made. As evidence thereof the Applicants provide copies of the USPTO patent recorded assignments database as accessed on February 9, 2010 (Appendix A).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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